IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 20-125 (LPS)
v.	)	(CONSOLIDATED)
	)	
ARCHERDX, INC., ARCHERDX, LLC and INVITAE CORP.,	)	**JURY TRIAL DEMANDED**
	)	
	)	**REDACTED - PUBLIC VERSION**
Defendants.	)	

NATERA, INC.'S LETTER BRIEF IN SUPPORT OF
NATERA, INC.'S MOTION TO COMPEL DISCOVERY

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Derek J. Fahnestock (#4705)
Anthony D. Raucci (#5948)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@morrisnichols.com
dfahnestock@morrisnichols.com
araucci@morrisnichols.com

Attorneys for Plaintiff Natera, Inc.

OF COUNSEL:

William G. Gaede, III
Bhanu K. Sadasivan
Jodi L. Benassi
MCDERMOTT WILL & EMERY LLP
415 Mission Street, Suite 5600
San Francisco, CA 94105
(650) 815-7400

Mandy H. Kim
MCDERMOTT WILL & EMERY LLP
18565 Jamboree Road, Suite 250
Irvine, CA 92612
(949) 757-6061

Original Filing Date: September 1, 2021
Redacted Filing Date: September 9, 2021

Dear Judge Stark:

Pursuant to the Court's Oral Order (D.I. 300), Plaintiff Natera, Inc. ("Natera") respectfully submits its letter regarding the outstanding discovery deficiencies.

I. RFP No. 9 (Design, Testing, Performance, and Sales of the Accused Products)

Although fact discovery closes this week, Defendants still have not produced certain documents related to how their products work and are used by their customers. The claims asserted in this case relate to specific methods for performing PCR. Natera seeks documents that show the specific materials used by Defendants' customers when performing any of the Accused Products. These materials for each of the Accused Products – which are express elements in Natera's asserted patents – include the nucleic acid sequence of each primer, the concentrations of the primers, the melting temperatures used in the PCR, the target loci and the nucleic acid input type. These documents are critical to Natera's analysis and showing of direct and induced infringement. Defendants have never denied the existence of the documents.

This issue is not new. Natera has diligently sought these documents throughout discovery and has brought the issue before the Court on two prior occasions. On January 19, the Court ordered Defendants to produce documents responsive to RFP No. 9 without waiting for the deadline for substantial completion of production. (D.I. 125.) Defendants failed to do so. Then, on April 26, the Court ordered Defendants to produce responsive documents for six customers by April 30, 2021. (D.I. 184.) Defendants again failed to produce sufficient documents that show the precise primers used, the melting temperatures and the concentration of each such primer, and the target loci and nucleic acid input type used by each of the six customers. On June 21, just before the next discovery hearing with the Court, Defendants represented to Natera that they would finish supplementing their responses to RFP No. 9 by July 9. *See* Ex. 1. For the third time, Defendants again failed to do so.

The Court has urged the parties to reach agreement on a representative number of customers. Natera was agreeable to that, and ultimately proposed reducing from 103 of Defendants over 300 customers for over 325 unique versions of the Accused Products to 22 customers that were representative. These were a "set of representative customers" pursuant to the Court's suggestion (D.I. 168) that they represent the majority of Archer's sales of the Accused Products and use of each of Accused Products. Defendants have steadfastly refused, limiting it to six customers that are not representative because they represent a small portion of Archer's sales and do not cover all of the Accused Products. *See* Ex. 2. Under Rule 26, Natera has reasonably narrowed its request and asks the Court to Order Defendants to produce responsive documents as to the following customers: [redacted], and the original six customers.

Information relating to how customers use Defendants' products is of obvious and critical relevance because it is directly related to Natera's inducement claims. Defendants initially resisted producing this information because the request was purportedly overly burdensome. During the

April 1 hearing, the Court suggested that it could easily see Defendants arguing that manuals alone might be insufficient to prove intent for inducement, recognizing the need for more information. Natera's request under Rule 26 to the 22 representative customers is reasonable. By contrast, artificially limiting discovery to just 6 of its customers, as Defendants would maintain, ensures that Natera will not have sufficient discovery under Rule 26 in this competitor litigation.

Defendants also refused to produce any documents providing the above technical information for any customers, where the document and information itself was not provided to the customer. *See* Ex. 3. For example, technical information on the primers, including their structure, is not specifically provided to the customers, but is crucial to Natera's infringement allegations (both criteria are elements of the asserted claims). Defendants' refusal to produce on this ground inhibits Natera's ability to establish infringement. In sum, Natera requests the Court to order Defendants to immediately produce sufficient documents that identify the nucleic acid sequence of each primer, the concentrations of the primers, the melting temperatures used in PCR, the target loci, nucleic acid input type, and PCR conditions used by each of previously agreed upon 6 customers as well as the 16 customers identified above.

II. RFP No. 1 (FDA Documents)

Natera requests the Court compel Defendants, in response to RFP No. 1, to produce documents relating to a March 8, 2021 meeting with the FDA regarding Defendants' Stratafide product. In that meeting, the "[redacted]" Ex. 4, 8/4/2021 email. Natera's RFP No. 1, in relevant part, seeks documents and communications relating to the FDA approval or authorization (or seeking of FDA approval or authorization) of Stratafide. On August 31, 2020, in response to RFP No. 1, Defendants agreed to produce responsive documents. *See* Ex. 5. But they have not supplemented their production with documents related to the March 8 meeting. Defendants' communications with the FDA are relevant because they describe whether a particular use of the Accused Product is or is not required for FDA approval, which goes to the heart of Defendants' alleged safe harbor affirmative defense under 35 U.S.C. Section 271(e)(1). Compelling documents relating to these meetings is not burdensome, but is important discovery on the merits of Defendants' affirmative defense. *See also* email explaining that Defendants' denying discovery on this factual issue is unwarranted. Ex. 4.

III. Interrogatory No. 2 / RFP No. 8 (Archer's use of the Accused Products)

Natera requests the Court compel Defendants in response to Interrogatory No. 2 and RFP No. 8 to produce documents sufficient to show the number of times they have used the Accused Products since January 21, 2020 – the date the first asserted patent issued. *See* Exs. 5-6. Such information is critical to Natera's damages theories. But Defendants refused to provide such information on the ground that certain uses automatically fell under their claimed affirmative FDA Safe Harbor defense. To allow Natera to test this, the Court ordered Defendants to "produce [ ] a supplemental interrogatory response indicating the safe harbor uses, what purpose, [ ] how they're tied to specific regulatory FDA filings, and at the same time [ ] produce documents sufficient to show that what [Defendants] have represented in [its] interrogatory is correct." *See* D.I. 246, at p. 14. Defendants' subsequent response shows uses that plainly ***do not fall within*** the scope of the safe harbor. Ex. 6; *see also* August 4, 2021 email explaining Defendants' reliance on 21 CFR §

820 for the wholesale application of the safe harbor is unsupported under the law. Ex. 7. Defendants' assertion that it is too burdensome to produce use numbers "that fall under the safe harbor" rings hollow. Defendants' own witness, Robert Daber testified that [redacted]

- Defendants refuse to designate a witness for Topics 1-2 to testify about the identity of persons substantively involved in the design and development of the Accused Products and its underlying AMP technology. *See* Exs. 9-10. Preparing a corporate witness to testify about these topics is not unduly burdensome and highly relevant to Natera's infringement analysis.

- Defendants refuse to designate a witness for Topic 9 to proffer testimony relating to Defendants' past, future, or contemplated filings with the FDA for its Accused Products. *See* Ex. 11. Information relating to Defendants FDA filings is relevant to Defendants' assertion of the affirmative Section 271(e) safe harbor defense. *See also supra,* Sec. II, III.

- Defendants refuse to designate a witness for Topic 10 on product design for customers unless Natera agrees to limit the scope of testimony to six customers and three categories of documents identified in the April 9 Joint Status Report (D.I. 175). *See* Ex. 11. Product design information is directly relevant and crucial to Natera's infringement claims and Natera has reasonably agreed to limit it to the 22 customers that are representative. *See* Ex. 2.

- Defendants refuse to designate a witness for Topics 17, 20-21, 22, which seek testimony relating to Defendants' inventory, insurance coverage, and reimbursement rates. *See* Ex. 11. Factual information relating to insurance coverage, reimbursement rates, and inventory of the Accused Products is directly relevant to damages and injunctive relief.

- Defendants refuse to designate a witness for Topics 45-46, which seeks testimony regarding Invitae's valuation of Archer and Genosity. *See* Ex. 11. [redacted] and such valuation information is relevant to damages and injunctive relief.

- Defendants refuse to designate a witness for Topics 39b and 50, which seek testimony relating to Defendants' affirmative defenses. *See* Exs. 10-11. First, Defendants rely on its partner hospital's development (known as MGH) of certain accused AMP technologies as Section 102(g) prior art, but refuse to designate a corporate witness on knowledge of that hospital's activities. Defendants certainly have such knowledge as Defendant Archer affirmatively pled in another litigation a long history of work with MGH relating to the accused AMP technology. *See ArcherDX, Inc., et al. v. Qiagen Sciences, LLC, et al.*, Case No. 18-cv-01019, D.I. 1 at ¶¶ 22-37. Defendants plainly have corporate knowledge of the same technology. With respect to Topic 50, Defendants plead Natera's relief is barred by unclean hands because of alleged acts by a senior Natera executive, who (i) left Natera, (ii) joined Defendant Archer, and (iii) subsequently went back to Natera and allegedly disclosed information – even though Archer subsequently dismissed trade secret misappropriation claims. Discovery is required.

Respectfully,

/s/ Derek J. Fahnestock

Derek J. Fahnestock (#4705)

DJF/lo
Attachments
cc: All Counsel of Record (*via* CM/ECF and e-mail)